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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|-------------------------|------------------------|
| 10/656,192 | 09/08/2003 | Mark J. Cooper | 003659.00029 | 8424 |
| 22907 | 7590 | 06/06/2007 | | |
| BANNER & WITCOFF, LTD. 1100 13th STREET, N.W. SUITE 1200 WASHINGTON, DC 20005-4051 | | | EXAMINER LONG, SCOTT | |
| | | | ART UNIT 1633 | PAPER NUMBER |
| | | | MAIL DATE 06/06/2007 | DELIVERY MODE PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|-------------------------------|-------------------------------|--|
| Office Action Summary | Application No. 10/656,192 | Applicant(s) COOPER ET AL. | |
| | Examiner Scott D. Long | Art Unit 1633 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-14, 17-19, 26, 28, 30-31, 34-40, 51-55, 58-70, 73-82, 102-104, 106-107, 109, 114-115, and 122 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 1-5,7-14,17-19,26,28,30,31,34-40,51-55,58-70,73-82,102-104,106,107,109,114,115 and 122.

DETAILED ACTION

The examiner acknowledges receipt of Applicant's REMARKS, Statement regarding claim 102, and claim amendments, submitted on 26 February 2007.

Claim Status

Claims 1, 7, 8, 11-14, 17, 26-31, 34-36, 78-81, 83, 104, 106-107, 109, 114-115 are amended. Claims 6, 15-16, 41-42, 56-57, 71-72, 108, 116-117 are cancelled. Claim 102 has been rejoined to this group, as requested by applicant. Claim 102 was inadvertently omitted from the group by an oversight of the applicant in designating which claims read on the elected species. Applicant suggests (AMENDMENT – After Non-Final Rejection, filed 2/26/2007) that the subject matter of the originally filed claim 102 is rejected over each of Wolff and Hanson, as described in the Action filed on 8/28/2006. Claims 1-5, 7-14, 17-19, 26, 28, 30-31, 34-40, 51-55, 58-70, 73-82, 102-104, 106-107, 109, 114-115, and 122 are under current examination.

Oath/Declaration

The oath has been reviewed by the examiner. The examiner thanks the applicant for pointing out that the petition requesting removal of an inventor was been granted on December 3, 2001. The oath is in compliance.

Priority

This application claims benefit from U.S. Application No. 2002/0042388 (abandoned), filed 31 May 2001, provisional U.S. provisional Application No. 60/287,419, filed 31 May 2001, and U.S. provisional Application No. 60/207,949, filed 31 May 2000. The instant application has been granted the benefit date, 31 May 2000, from the application 60/207,949. However, it must be noted that the provisional application makes no mention of lyophilization or disaccharides.

Response to Arguments - Claim Rejections 35 USC § 112

Response to Arguments – ENABLEMENT (35 USC 112, first paragraph)

Applicant's arguments filed 26 February 2007 have been fully considered but they are not persuasive.

The applicant has argued that independent claims 1, 8, 17, 26, and 28 have been amended "to clarify that the composition need not be homogeneous, *i.e.* that all complexes in the composition need not be rod shaped." (REMARKS, page 22, first parag.). However, the examiner disagrees with the assertion that the amendments are now directed to a heterogeneous mixture of complexes. The examiner fails to see any change in scope, as a result of amendment, that is directed to the shape of the complexes. The above cited claims still recite, "said complexes are rod-shaped" (for example, claim 1, lines 6-7, emphasis added). The amendments of claim 1, lines 1-3, for example, seem to mean that the composition is composed of a multitude of

complexes that consist of one DNA molecule and one or more polycation. There seems to be no mention of the shape of the complexes, in these amendments. Claim 1, lines 1-3, for example.

The examiner reasserts the reasoning for his previous 35 USC 112, first paragraph rejection, below:

In the instant case, claims 1-5, 7-14, 17-19, 26, 28, 30-31, 34-40, 51-55, 58-70, 73-82, 102-104, 106-107, 109, 114-115, and 122 provide for no other shape except rod-shaped complexes. However, the instant application is not enabled for a composition wherein said complexes are all rod-shaped particles nor is the application enabled for a method of separating rod-shaped from all other shaped particles. There is insufficient support in the specification for this limitation.

Most of the specification is drawn to compositions wherein said complexes are in the shape of a condensed sphere. Additionally, there is some support in the specification for compositions wherein the shapes of the complexes are a mixture of shapes, including spheres, toroids, relaxed toroids, toroids with tails, Y-shaped rods, small and large rods. Therefore, the nature of the invention seems to be for compositions that are more than merely rod-shaped complexes. In fact, the electron micrographs provided in the drawings of the instant application show mixtures of shapes (see Figure 10, Acetate panel and Figure 13 and Figure 17). Furthermore, Kwoh et al. teach "PLLs of all sizes condensed plasmid DNA into toroidal and rod-shaped structures" (page 179, section 3.4), indicating that the state of the art teaches a mixture of shapes is usual outcome of condensation methods that use PLL. Nowhere, in the

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working examples, of the instant application is there support for or instructions detailing how to make a composition of complexes that are only rod-shaped nor is a method of separating rod-shaped from other shaped particles described in the specification.

The examiner cannot understand from the specification why the invention is directed to only rod-shaped complexes. Furthermore, the specification does not teach why the particular sizes and shapes are important to the invention.

Therefore, the quantity of experimentation required to make and use the invention, as claimed, is insufficient to enable the invention.

A second rejection of the instant claims was made under 35 USC 112, first paragraph, regarding lack of enablement for compositions and methods of delivery to cells, wherein the intended use is for gene therapy applications.

The applicant attempts to overcome the examiner's rejection by citing Konstan et al, Human Gene Therapy, (2004), 15:1225-1269. The applicant points out that Konstan et al. utilize similar compositions as are claimed in the instant application with some success at reconstituting Cystic Fibrosis Transmembrane Regulator (CFTR) function. While this, at least partial success, was demonstrated by Konstan et al. in 2004, the examiner would like to point out that the benefit date of the instant application is 31 May 2000. Among other factors, the rejection is based on the state of the prior art at the time of the instant invention. The examiner asserts that this post-art does not enable the instant invention.

Therefore, the rejection of claims 1-5, 7-14, 17-19, 26, 28, 30-31, 34-40, 51-55, 58-70, 73-82, 102-104, 106-107, 109, 114-115, and 122 under 35 USC 112, first paragraph is hereby maintained.

Response to Arguments - Claim Rejections 35 USC § 102

Applicant's arguments filed 26 February 2007 have been fully considered but they are partially persuasive.

The applicant argues that the rejection of claims 1-2, 8-9, 11-12, 17, 20, 26, 28, 38 and 102-104, are rejected under 35 U.S.C. 102(b) as being anticipated by Wolff et al (US-6,126,964) should be withdrawn because the Wolff reference does not teach the limitations of the newly amended claims directed to the 10-20 nm diameter size of the rod-shaped complexes.

The examiner agrees with the applicant, that the Wolff et al. reference does not teach rod-shaped DNA complexes having a 10-20 nm diameter.

Therefore the examiner withdraws the rejection of claims 1-2, 8-9, 11-12, 17, 20, 26, 28, 38 and 102-104, under 35 U.S.C. 102(b) over Wolff et al.

The applicant argues that the rejection of claims 1-2, 8-9, 11-12, 17-18, 26, 28, 30, 34, 36, 38, 53, 65, 78, 85, 92 and 102-103 under 35 USC 102(b) as being anticipated by Hanson (US 5,844,107) should be withdrawn because the Hanson

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reference does not teach the limitations of the newly amended claims directed to the 10-20 nm diameter size of the rod-shaped complexes.

Despite the applicant's assertion, Hanson teaches, "rod-like fibers... 10-20 nm thick" (Table 103, col. 57-58, Electron Microscopy section). Therefore, Hanson teaches all the limitations of the instant claims.

Therefore, the rejection of claims 1-2, 8-9, 11-12, 17-18, 26, 28, 30, 34, 36, 38, 53, 65, 78, 85, 92 and 102-103 under 35 USC 102(b) as being anticipated by Hanson (US 5,844,107) is hereby maintained.

Response to Arguments - Claim Rejections 35 USC § 103

Applicant's arguments filed 26 February 2007 have been fully considered but they are not persuasive.

The applicant argues that the 35 USC 103 rejections cited below should be withdrawn, because they use Hanson as a primary reference and use secondary references merely to supply a teaching of a recitation in a dependent claim.

The rejection of claims 3, 10, 19, 31, 35, 37, 51-53, 63-65, 67-68, 76-78 and 104 under 35 U.S.C. 103(a) over Hanson, Park, and Schacht.

The rejection of claims 58-62, 66, 73-75, 79-82, 122 under 35 U.S.C. 103(a) over Hanson, Park, Schacht, and Mao.

The rejection of claims 4-7, 13-16, 39-42, 54-57, 69-72, 106-109, and 114-117 under 35 U.S.C. 103(a) over Hanson, Park, Schacht, and Kwoh .

Since Hanson does teach all the limitations of the independent claims, as cited above in 35 USC 102(b), and the 102 Hanson rejection has been maintained, the argument supplied by the applicant is moot.

Therefore, the rejections of the cited claims under 35 USC 102(b) as being obvious over the three 35 USC 103 rejections, above, is hereby maintained.

Double Patenting

The applicant did not respond to the rejection made in the previous action, filed 8/28/2006. The examiner reiterates his rejection below.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5, 7-14, 17-19, 26, 28, 30-31, 34-40, 51-55, 58-70, 73-82, 102-104, 106-107, 109, 114-115, and 122 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 41-43, 93-94, 96-97, 155-159, 182 of U.S. Patent Application No. 20030134818. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claims 41-43, 93-94, 96-97, 155-159, 182 of the cited application are directed to methods of preparing a composition of nucleic acid-PEG-PLL complexes, having counterion of acetate, and characterized by electron microscopy. Claims 1-19, 26, 28, 30-31, 34-42, 51-82, 103-104, 106-109, 114-117, and 122 of the instant application are directed to the product created by the process of the cited application. Furthermore, the specifications for the two applications appear to be identical.

Accordingly, instant claims and the claims of the cited application are obvious variants. Therefore, the inventions as claimed are co-extensive.

Claims 1-5, 7-14, 17-19, 26, 28, 30-31, 34-40, 51-55, 58-70, 73-82, 102-104, 106-107, 109, 114-115, and 122 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 10-14, 16-19, 184, 199-200 of U.S. Patent Application No. 20030171322. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claims 10-14, 16-19, 184, 199-200 of the cited application are directed to methods of preparing a composition of nucleic acid-PEG-PLL complexes, having counterion of acetate, and characterized by electron microscopy. Claims 1-19, 26, 28,

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30-31, 34-42, 51-82, 103-104, 106-109, 114-117, and 122 of the instant application are directed to the product created by the process of the cited application. Furthermore, the specifications for the two applications appear to be identical.

Accordingly, instant claims and the claims of the cited application are obvious variants. Therefore, the inventions as claimed are co-extensive.

Conclusion

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

No claims are allowed.

Examiner Contact Information

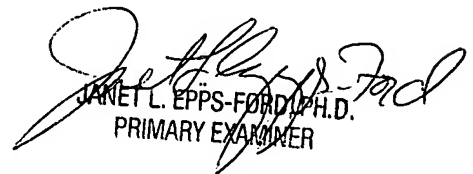
Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Scott Long** whose telephone number is **571-272-9048**.

The examiner can normally be reached on Monday - Friday, 9am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Woitach** can be reached on **571-272-0739**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Scott Long
Patent Examiner
Art Unit 1633


JANET L. EPPS-FORD, Ph.D.
PRIMARY EXAMINER